DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

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Abstract

This report summarizes activity over the period from January 2000 through May 2000 on NIH Contract N01-DC-7-2103. "Development of a High Density Percutaneous Connector System". The six implants reported at HMRI last quarter have been sacrificed; these are the final implants on this contract. There are promising materials and construction methods being tested to reduce electrical leakage. The first prototype quick disconnect mechanism has been delivered to NIH. This contract is operating on a no cost extension through June 2000 and this report covers activity for the extra month to May 15th.

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I. Background and Review of Contract Requirements

This report summarizes activity during the specified quarter, on NIH Contract N01-DC--2103. "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.
- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.
- The connector will be designed from materials that are durable and can withstand
 the physical abuse from normal activities of daily living. The interface between the
 connector and the skin must be such that the passage of microorganisms into the
 body and fluid drainage out of the body is prevented.
- In earlier studies connectors had five separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies, it is necessary to make a more durable and a more realistic part. The present cable is a ribbon one-inch long with five 2-mil Pt Ir wires, coated with Parylene and Silicone. The wires are looped so there are five loops for testing. The 2 mil wires are more rugged and easier to work with for initial tests, but 1 mil wires will be used after the ribbon cable concept is developed. An 18-Volt bias will be maintained on the wires relative to an implanted platinum wire connected to one of the unused contacts or the Ti connector body. The leakage current of the cable wires will be monitored with a maximum acceptable value of 10 nanoamperes.

- Performance of the connector system will be tested in a suitable animal model. After
 three to six months of implantation, the connector assembly will be explanted and
 gross and microscopic examinations will be performed to study the attachment of
 the pedestal to the skull, the attachment of the skin and soft tissue surrounding the
 pedestal to the pedestal wall and the reaction of adjacent tissue to the implanted
 device.
- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation. Initial testing will be in cats with final tests conducted in non-human primates.

H. HMRI Work

Five of the six cats implanted with percutaneous devices at Huntington Medical Research Institute have been sacrificed with a histology report expected in June. One implant was lost early in this work. The percutaneous connector was removed (tc46) and the pedestal reimplanted in another animal (tc49) so all six remain active experiments with five involving skin healing and attachment, osseointegration, electrical leakage and cable viability. Two of the six animals wore bias packs as has been the practice: the others have not had bias on the implant cables except when measurements are being made.

Two connector core designs were used as described in QPR #11. The individual animals with a summary of results are:

Number	Core Type	Status as of May 12, 2000	Skin Attachment	Electrical Leakage (nA)
tc43	epoxy	sacrificed	Infected - puss	1.7 2.6
tc44	epoxy	sacrificed	good	250 failed
tc45	epoxy	sacrificed	good	70 uA failed
tc46	epoxy	lost, ped in tc49	N. A	2 - 3
tc47 *	ceramic	sacrificed	good	0.17-0.37
tc48 *	ceramic	sacrificed	good	0.14 0.19
tc49	N.A ped only	alive	N/A	NA

Table 1. Summary of Feline Tests.

The condition of the cable loops was reported, but the results were inconsistent and not summarized above. For example, tc43 showed all loops open on Feb 17th and all loops good on March 3rd. Such results have been seen before and are attributed to anisotropic elastomer failure. On implants reporting open loops in the past, two were recovered because of loss of the implant. When these were examined all loops were intact, there was no sign of any damage at any point in the loop and a somewhat extreme flexing of the cable would not make it fail. The

^{*} tc47 and tc48 had ceramic surface cores; others had a single internal ceramic.

only questionable result in this set of experiments was tc48 with loop 4 consistently open after. March 27th

The bone integrations at the time of the second surgery were all good. Skin integration has been good except in one animal (tc43) that had a progressive infection. The skin attachment was lost and, as speculation and from experience, the osseointegration would probably have been lost if the experiment continued for another month. This is the normal course when infection reaches a level where antibiotics do not clear it. From observation during the experiment the other skin attachments have been good; histology will be necessary to know the entire story.

III. Electrical Leakage

Electrical Leakage has been a problem through this entire contract. Reports from the earlier contract (ending in March 1997) of excellent low leakage have not been repeated. The problem has been traced to a poor connector design (the gap between the Alumina pieces used to align the pins has voids that can cause currents of tens of microamperes) and the materials being used (the epoxy will eventually leak at several nanoamperes, in spec but too close). Attempts early in this contract to construct a solid ceramic core failed because a perform could not be manufactured with the small pin diameter required.

At present two methods are being investigated in vitro to reduce electrical leakage: use of a ceramic core manufactured by laser machining and a hydrophobic cynate ester manufactured by Ciba. Arocy XU366. In addition, modified cores have been used in the implants at HMRI. One type has a ceramic surface with modified EpoTek 301 under it (tc47 and tc48) and the second has a single internal ceramic pin alignment part with the EpoTek 301 above and below it. Experience has shown that both of these designs will eventually leak at the several nA level because of the materials. However, the extreme high levels should be eliminated.

The results of the in vivo leakage tests at HMRI are mixed. Two implants, tc43 and tc44, failed on the first measurement with leakages from 250 nA to 70 uA. The cause of the problem is not known. Data was not taken on tc44 and tc45, tc49 had no cable. However, data on the other implants is shown in tables below.

Date	Loop 1	Loop 2	Loop3	Loop 4	Loop 5
2 17 00	0.015	0.012	0.010	0.008	0.120
3:3.00	0.38	0.39	0.33	0.48	0.38
3.27	0.78	0.58	0.25	0.45	0.27
4 21 00	0.58	0.63	0.71	0.92	0.90
5 11 00	2.3	2.6	2.4	1.7	1.8

Table 2. Electrical Leakage in nA on tc43.

Date	Loop 1	Loop 2	Loop 3	Loop 4	Loop 5
2/17/00	6.0	5.8	3.5	4.3	3.7
3 3 00	1.04	0.84	1 12	1.04	1.1
3.27.00	0.31	0.18	0.14	0.14	0.2
4/21/00	0.19	0.21	0.17	0.15	0.12
5 11 00	0.37	0.31	0.28	0.19	0.17

Table 3. Electrical Leakage in nA on tc47.

Date	Loop 1	Loop 2	Loop 3	Loop 4	Loop 5	
2 17.00	0.30	0.44	0.32	0.32	0.38	
3/3/00	0.98	0.84	1.00	0.30	0.78	
3,27.00	0.78	0.58	0.25	0.45	0.27	
4:21:00	0.25	0.24	0.25	0.37	0.33	
5 11 00	0.15	0.14	0.14	0.14	0.19	

Table 4. Electrical Leakage in nA on tc48.

Date	Loop 1	Loop 2	Loop 3	Loop 4	Loop 5	
2 17 00	6 ()	5.8	3.5	4.3	3.7	

Table 5. Electrical Leakage in nA on tc46 before it was lost.

Two implants, tc46 and tc47 started with leakage greater than 1 nA. The leakage on tc47 dropped rapidly to the 200 to 400 pA range. The leakage for tc48 started around the 400 pA level and dropped to 150 to 200 pA. This drop in leakage has not been seen before. Either there is a new leakage mechanism with the new core geometries or the first measurements were in error which may raise the question as to whether tc43 and tc44 were really as high as they measured.

The conclusions that are drawn from this data and the history throughout the contract is that:

- The double Alumina pin alignment was a bad design.
- The single Alumina pin alignment at the surface or internal is an improvement although two of the internal design parts showed extreme failure for unknown reasons. It is thought that the failures are manufacturing, not design, problems.
- Accelerated aging showed that the modified EpoTek 301 will leak near 5 nA over a long lifetime. This is below the 10 nA limit, but is not acceptable.
- Ceramic performs could not be made with 0.018 inch diameter pins.
- For manufacture a clean, controlled environment (not a clean room) is essential, gloves and mask must be used and cleaning at several critical manufacturing points is required.

After polishing the PGA surfaces they must be treated as free of organic matter and not touched. Parts must be stored in clean containers during manufacture when not actually being worked on.

- Removal of voids (bubbles) in the polymers is critical.
- Spot welding of the wires followed by cleaning is preferred over soldering, but soldering with various fluxes is possible if the part is rinsed immediately and sonicated within less than one hour. Both processes are inherently dirty. Some solder flux can damage the core polymer.
- The cable is not a source of leakage at the levels observed.
- Better core material (polymer) and use of a ceramic core both hold the possibility of a long-life. low-leakage design. The ceramic core is almost certainly better, but has difficulties.
- Use of Tetraetch on the Teflon wire dielectric is necessary to achieve a bond to the polymers used (Silicones, epoxy and others). This removes a leakage path along the wire

Taking the data at face value it is certainly possible with this length experiment to make an acceptable implant although there are problems with excessive leakage in some, probably resulting from manufacturing problems, that must be eliminated. This is best done in vitro. From experience the leakage in the good implants, with the epoxy used, would be expected to increase to marginal levels over a period of months to years.

An in vitro experiment with modified EpoTek 301 as a control, the Ciba XU366 and a ceramic core design is in progress. The resulting data will be sent as a supplement to this report. In QPR #11 it was reported that on a single measurement after two weeks at 60°C in Ringers a 301 sample showed 200 pA of leakage and the XU366 showed less than 10 pA. The purpose for the experiment in progress is to obtain a more complete history of the leakage in these dielectrics as well as a ceramic core.

IV. Quick Disconnect

The first prototype of the quick disconnect mechanism reported in QPR #11 was delivered to NIH during this period. This prototype closed with a good torque level of 8 oz in. Because of the forces on steel internal parts there was some deformation which caused a slightly lower compression on the anisotropic elastomer than is needed. The deformation problem is being cured by increasing the number of bearings and hardening the steel in the second prototype. A more complete report on this work in contained in Appendix I.

V. Skin Attachment

A grooved Titanium skin attachment surface used in the last contract and early in this one did stop epithelial downgrowth in a significant number of experiments, but downgrowth and infection were still common problems. With the beaded Titanium surface downgrowth and infection have become the uncommon exception. The quantity of data is not sufficient to compare the two surfaces objectively, but experience certainly indicates that the beaded surface

is superior. As conjecture, the reason is a deeper structure into which cells can grow with a more random geometry than the horizontal grooves so cells, especially fibroblasts, require a less specific orientation to attach allowing more cells to achieve attachment.

Both the dermis and epidermis must attach to the connector for a good long-term implant. There is no reason to expect the two skin layers to need similar surface conditions for attachment. The beaded surface, because of its more random geometry, presents a variety of conditions making it more likely that both skin layers can find suitable conditions. Only one bead size, 150 micrometer diameter, was used in this work. It is likely that another size or a mix of sizes would be more optimum

Infection remains the major reason for loss of skin integration and can lead to loss of established osseointegration and the entire implant. Identifying the infection source has not been an objective. The protocol has been to treat with antibiotics and keep the wound clean until healing and attachment occur. A significant step toward reduction of infection would be to minimize the healing time. Two implants used Laminin-5 supplied by UWEB at the University of Washington to aid epidermal healing. The procedure seemed to be successful and worth pursuing along with other bioactive surfaces in the future. The major objective in this work has been to obtain a stable long-term attachment surface and this should probably remain the objective until the beaded surface is more thoroughly understood.

Manufacturing of the beaded surfaces was a problem through the last year and a half. The furnace used to sinter the parts has a volume of approximately 0.5 cubic yard, draws a vacuum and runs a sixteen to eighteen hour cycle with a variety of parts being sintered simultaneously. (Externally the furnace is the size of a small room and the vacuum chamber rolls out on railroad tracks.) Compared to hip replacement and other parts with which these beads are fired, our parts, both the skin ring and the pedestal for osseointegration, are small. A routine and minor alteration was made to one of the zone heaters in the furnace early in 1999 and the beads came out as "lumps" instead of spheres although larger parts were okay. This was caused by a change of a few degrees during the sintering (firing) process. The quick cure was to make the parts attached to a large bulk or thermal mass of Titanium and then re-machine them after sintering. This took extra time and money, but resulted in a usable surface.

VI. Osseointegration

Osseointegration is measured on a linear scale instead of an area at HMRI. The percentage of integration has increased from 30 to 40% to 80% or better. A key to obtaining this improvement is in the fit of the connector pedestal to the prepared skull. A gap of more than one to two cell diameters (osteoblasts) is apparently difficult to impossible to be bridged. Methods of making the surgery less critical have been discussed, but not yet tried.

The pedestal has two screws located inside its 0.5" diameter for skull attachment. Ears outside the major diameter are a wrong method because they can not be tightened in a way to avoid tilting the pedestal and causing an unacceptable gap across which the osteoblasts can not jump to obtain osseointegration. This was learned in related work.

VII. Additional Reports Needed

This completes the work on this contract except in two areas. The histology must be completed at HMRI and the results of electrical leakage tests are required. These will be submitted as supplements to this report.

VIII. Conclusions

- Skin attachment has been improved with the new beaded surface.
- Osseointegration is good and continues to improve with experience.
- The new pedestal and cable designs have resulted in a reliable cable.
- The ShinEtsu anisotropic elastomer has reliability problems.
- The quick disconnect design prototypes are successful.
- Electrical leakage is still a problem, but there seem to be usable methods to reduce it to an acceptable level.
- The solid ceramic core remains a desired goal to reduce electrical leakage and improve reliability and length of implant. It may be necessary to reduce the number of pins to 49 or 36 to obtain usable performs.

The percutaneous planar grid array design appears to be successful or near success in all areas except the elastomer problem. While skin attachment is not completely solved, and won't be within the scope of this work, it appears that the beaded surface is significantly better than other available surfaces for stopping epithelial downgrowth and providing a surface for long-term skin attachment.

Appendix I Quick Disconnect Report

The 64 Channel Percutaneous Connector with Quick Disconnect Upper Stage

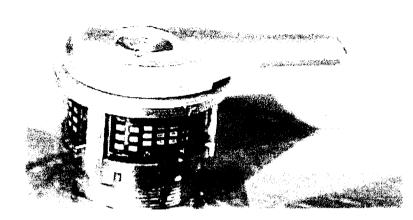


Figure 1. The prototype "QD5" upper stage is shown mated to a portion of the lower stage. To complete the assembly, wires are soldered to the rectangular pads and the cable bundle jacketed and potted as shown in figures 6-8.

One goal of the Percutaneous Connector contract is to develop a "quick disconnect" feature which allows the upper connector stage ("UCS") to be quickly and easily mated to the lower connector stage ("LCS") Successful incorporation of a quick disconnect into the connector design will be of great benefit to researchers. A convenient quick disconnect is also considered vital to the effort to develop a percutaneous connector for human implant.

The design goal has been to leave the lower connector stage, which is implanted percutaneously, largely unchanged in design and materials and thus build on the extensive research and development effort which has already gone into its construction. The UCS, which is not implanted, would be completely redesigned to incorporate the features required to allow a quick disconnect. Minor modifications of the LCS would most likely be required to provide mating or grasping features for the UCS, but these changes would be kept to a minimum.

The Quick Disconnect design effort began in earnest in May of 1998. The design is extremely challenging to implement due to the high contact density, low profile, and limited modification of the LCS which are strongly desired in this design. The challenge is compounded by the very high connection force required by the anisotropic conductor which is used to establish electrical connection between the mating connector halves. Five quick disconnect designs, designated QD1 through QD5, have been conceived during the design effort, with varying degrees of development effort being invested in each design. The QD5 design was deemed sufficiently promising to justify construction of prototypes in the fourth quarter of 1999 and first quarter of 2000. A proof-of-concept prototype was delivered to the program manager in May of 2000. This connector, titled "64 Channel Percutaneous Connector with Quick Disconnect Upper Stage" is based on the QD5 quick disconnect design.

In the summer and fall of 1998 a prototype connector incorporating a first quick disconnect design, "QD1", was designed and an initial prototype fabricated. This design added a fine thread to the outer diameter of the LCS and redesigned UCS to include a threaded ring which screwed onto the LCS. Functional testing of this prototype demonstrated that an unacceptably high level of torque was required to compress the anisotropic conductor with sufficient force to make complete, reliable electrical contact.

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Subsequent to this, torque and force tests were performed to establish the physical and electrical properties of the relevant materials QD1 components were fabricated from a number of low-friction materials, and lubricants were tried as well, in order to yield a connector with the lowest possible requisite compressive force This testing revealed that the anisotropic conductor may required up to 70 pounds of compressive force to establish full connectivity, although full connectivity was often achieved with as little as 30 pounds of compressive force. The coefficients of friction of several low-friction materials were measured for this application, along with the metal-on-metal coefficient of friction achieved with selected lubricants.

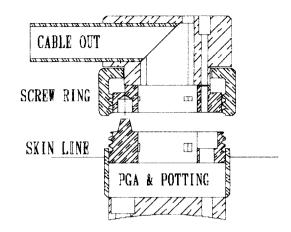


Figure 2. The "QD1" design. Friction in the screw threads made this design impractical.

The conclusion of this testing program was that no low-friction material or lubricant system would reduce the torque of the QD1 design to an acceptable level. A "feel" test was performed which established 10 oz-inches as the maximum allowable torque of future designs with 6 oz-inches being a more desirable target.

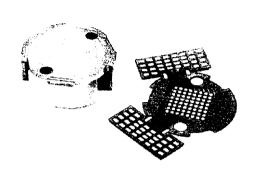
Table 1. A simple test stand was constructed mating a ½" knurled knob with a torsion balance. The results were reported subjectively by the operator. This data gives an estimate of the allowable operating force of any connector design that twists to connect.

Torque (ounce-inches)	Results
34	Limit of test fixture. Approaching limit of operator strength.
25	Firm twist. Would probably cause skull discomfort or trauma.
10	Firm but probably allowable. Maximum recommended.
6.6	Moderate. Likely to meet with broad acceptance.
3	Light to moderate. Probably OK for arthritic fingers.

Two directions were seen as possible ways to enable a quick disconnect design. The first was to develop a replacement for the anisotropic conductor that would reduce the requisite compressive force by a factor of four or better. The second was to implement a mechanical design which incorporated a rolling element bearing, force multiplying cam or lever, or some other mechanical linkage which would enable the connector to compress the anisotropic conductor with sufficient force while requiring only minimal force or torque to be applied by the user.

An effort to develop a replacement for the anisotropic conductor was carried out in the fourth quarter of 1998 and the first quarter of 1999. Although some results were very promising, no solution was found which met the requirements of consistency, durability, and contact density.

An effort to replace the labor-intensive pin grid array in the UCS with a batch-fabricated flex circuit and/or flex or ribbon cable was carried out in the first and second quarters of 1999. The conceptual designs and material evaluations developed therein were incorporated into the QD5 quick disconnect prototype.



Figures 3 & 4:
The UCS pin array was replaced with a flexible circuit and solder pad array.
Shown at left before assembly to supporting shell component. At right, assembled.



The decision to retain the anisotropic conductor for use in the quick disconnect connector spurred the exploration of designs using mechanical force multiplication. The goal of this design is to devise a mechanical linkage which compresses the anisotropic conductor with a minimum of 35 pounds of force (70 preferred) while transmitting only 10 ounce-inches or less of torque to the skull and requiring a similarly light force to be applied by the user's fingers. The use of a ball-screw, or helical screw using rolling elements (ball bearings or roller bearings) to transmit the force within the screw, promised to meet these requirements of force and torque. Once the decision to design the UCS around a rolling element screw had been made, the balance of the design followed logically from this point. The mechanical design and documentation of the QD5 design quick disconnect was carried out in the fourth quarter of 1999 and first quarter of 2000.

Since the core of the QD5 UCS is used for bearing elements, there is no room for a conventional pin array as used on earlier designs. Therefore this design replaces the pin grid array with an array of circular pads in a flexible circuit. This circuit then routes these pads to rectangular solder pads which are wrapped around the outer circumference of a UCS component. A wire bundle may be soldered to these pads and formed into a cable which exits the connector. The outer surface is then encapsulated with a potting compound to immobilize and protect the wire terminations. This flexible circuit and its method of attach to its supporting structure within the connector was developed entirely in-house. The electrical circuit routing the pads of the UCS grid array out to the rectangular solder pads was machined from stock flex circuit laminate using BioElectric's frequency-quadrupled Nd:YAG laser. This novel technique produced electrical traces as small as 0.002" (50 microns) wide separated by 0.0005" (13 micron) spaces. This extremely high circuit density allowed each of the 64 pads to be routed to an individual rectangular solder pad using a single layer, single-sided circuit. The circuit was then encapsulated using a sheet coverlay material that had been laser machined to leave only the grid array pads and solder pads exposed. The development effort to design, fabricate, and mount the circuit took place in the first quarter of 2000. It involved an extensive test program to establish the proper processing parameters for these materials.

At the core of the QD5 UCS is a pea-sized inner bearing race that has several short ball-bearing races machined into its outer surface. Each bearing race follows a shallow helical

path. The base of this component also has a bearing race for a thrust bearing which allows it to transmit a strong axial load with very little resulting friction. The inner bearing race is

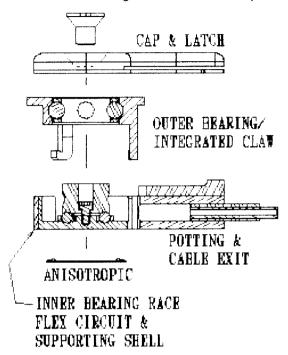


Figure 5. Exploded assembly view of QD5 design UCS.

attached to a cap which is machined to match the profile of the connector body and strain relief. Rotating this cap causes the inner bearing race to translate vertically with respect to the outer bearing race due to the helical cut of the bearing races. This in turn compresses the anisotropic conductor and makes electrical connection. The use of multiple rolling elements, a shallow helix angle, and a rolling element thrust bearing to transmit the force all contribute to this design delivering a powerful mechanical compression with minimum required torque. Furthermore, although the required torque is on the order of 8-10 oz-inches, and is therefore within the allowable maximum established earlier, in practice the cap is twisted by a "pinching" action, forcing it to rotate with respect to the balance of the UCS, which is stationary. This pinching action is used to force the cap into alignment with the lower portion of the UCS, which is formed to include a cable strain relief and latch plate. As such, this action transmits only a portion of the torque required to actuate it to the LCS and through it to the skull.

The outer bearing race incorporates three claws which engage along the outer edge of the LCS. Only one component of the LCS has been modified to accept the redesigned UCS. This "Chassis" component adds grooves along the outer circumference for the claws to mate to and adds two tapered alignment features on its upper surface to ensure proper alignment of the LCS and UCS pad arrays when the two components are mated. This chassis component is made of the same Titanium alloy as earlier non-quick-disconnect versions. The addition of grooves along its outer circumference increases the height by 2.7 mm over earlier non-quick-disconnect versions. The alignment features protrude an additional 1.2 mm and are made from high strength stainless steel. They thread into blind holes in the chassis face and are replaceable in the event of wear or damage.

In use, the UCS is prepared by rotating the cap counterclockwise to ensure that the claws are at full extension, and rotating the claws counterclockwise until they hit their stop with respect to the connector body (about 10° of travel). The UCS is then mated to the LCS and the claws turned CW to engage them. In the fully fabricated version, the cap is then rotated CCW until it is about 15° CCW from the strain relief; it is then rotated CW to compress the connector until it is aligned with the lower portion of the UCS, at which time a latch feature engages, holding it in place. A partially fabricated prototype has been delivered which does not include the potting and cable out portion of the UCS. This device "latches" without an external latch due to a detent which is incorporated into the bearing races. It may be latched with the cap in any position. This natural detent latch occurs at 8 oz-inches of torque and compresses the

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anisotropic conductor with a force of 20-25 pounds, which is slightly less than the desired 30 lb minimum.

This development effort is nearly complete under the current contract. Future efforts will be the fabrication of one or two additional prototypes of the QD5 design, documentation, cost estimation, and the design and fabrication of an improved inner bearing race. The existing prototype has demonstrated a strength deficiency in the inner bearing race. This will be corrected by increasing the number of bearings and races, thus distributing the load and allowing the connector to develop a larger compressive force on the anisotropic conductor. The component is made from a heat-treatable stainless alloy; heat-treating the completed part is being considered as an additional method of improving its strength.

